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<b>(21) International Application Number:</b> PCT/US00/16782 <b>(22) International Filing Date:</b> 15 June 2000 (15.06.2000) <b>(30) Priority Data:</b> 09/334,996 17 June 1999 (17.06.1999) US <b>(60) Parent Application or Grant</b> MINIMED INC. [/]; O. CAUSEY, James, D., III [/]; O. HAGUE, Clifford, W. [/]; O. MASTROTOTARO, John, T. [/]; O. VAN ANTWERP, William, P. [/]; O. KOVELMAN, Paul, H. ; O.	<b>Published</b>	
<b>(54) Title: CHARACTERISTIC MONITOR SYSTEM FOR USE WITH ANALYTE SENSOR</b> <b>(54) Titre: SYSTEME MONITEUR DE CARACTERISTIQUES UTILISE AVEC UN CAPTEUR D'ANALYTE</b>		
<b>(57) Abstract</b> <p>A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user includes a housing, a test strip receptacle, a sensor receiver and a processor. The test strip receptacle is for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte. The sensor receiver is used to receive sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the receiver and the test strip receptacle to process the determined quantity of the analyte and the sensor data signal from the at least one characteristic sensor. The characteristic monitor may further include a transmitter coupled to the processor for transmitting the processed signals to another data receiving device. Preferably, the transmitter transmits the processed signals by radio frequencies. The characteristic monitor may also include a display to show the determined quantity of the analyte and the processed signals from the characteristic sensor. In addition, the characteristic monitor can include a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. Also, the sensor data signals can be received by the sensor receiver continuously, near continuously, and/or intermittently.</p> <b>(57) Abrégé</b> <p>L'invention concerne un moniteur de caractéristiques s'utilisant dans un système équipé d'au moins un capteur de caractéristiques qui produit un signal indiquant une caractéristique d'un utilisateur. Le moniteur comporte un boîtier, un récipient à bande de test, un récepteur de capteur et un processeur. Le récipient à bande de test sert à recevoir et à tester la bande de test exposée à un analyte afin de déterminer la quantité de l'analyte. Le récepteur de capteur est utilisé pour recevoir des signaux de données de capteur produits par le(s) capteur(s) de caractéristiques. Le processeur est couplé au récepteur et au récipient à bande de test pour traiter la quantité déterminée de l'analyte et le signal de données de capteur provenant du/des capteur(s) de caractéristiques. Le moniteur de caractéristiques peut comporter en outre un émetteur couplé au processeur pour transmettre les signaux traités vers un autre dispositif de réception de données. De préférence, l'émetteur émet les signaux traités par radiofréquences. Le moniteur de caractéristiques peut comporter également un écran pour afficher la quantité déterminée de l'analyte et les signaux traités provenant du capteur de caractéristiques. Le moniteur de caractéristiques peut comporter en outre une mémoire pour stocker la quantité déterminée de l'analyte provenant du récipient à bande de test et les signaux de données de capteur traités provenant du/des capteur(s) de caractéristiques. De plus, les signaux de données de capteur peuvent être reçus par le récepteur de capteur en continu, de manière quasi continue et/ou intermittente.</p>		

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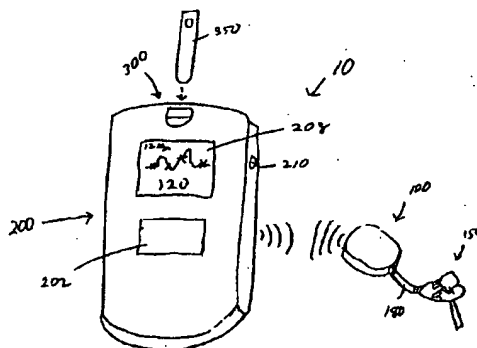
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- (71) Applicant: MINIMED INC. [US/US]; 12744 San Fernando Road, Sylmar, CA 91342 (US).
- (72) Inventors: CAUSEY, James, D., III; 2107 Cushman Court, Simi Valley, CA 93063 (US). HAGUE, Clifford, W.; 14570 Benefit Street, N° 303, Sherman Oaks, CA 91403 (US). MASTROTOTARO, John, T.; 10642 Lindbrook Drive, Los Angeles, CA 90024 (US). VAN ANTWERP, William, P.; 26833 Pinehurst Drive, Valencia, CA 91355 (US).
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- (74) Agent: KOVELMAN, Paul, H.; MiniMed Inc., 12744 San Fernando Road, Sylmar, CA 91342 (US).

(54) Title: CHARACTERISTIC MONITOR SYSTEM FOR USE WITH ANALYTE SENSOR



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(57) Abstract: A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user includes a housing, a test strip receptacle, a sensor receiver and a processor. The test strip receptacle is for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte. The sensor receiver is used to receive sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the receiver and the test strip receptacle to process the determined quantity of the analyte and the sensor data signal from the at least one characteristic sensor. The characteristic monitor may further include a transmitter coupled to the processor for transmitting the processed signals to another data receiving device. Preferably, the transmitter transmits the processed signals by radio frequencies. The characteristic monitor may also include a display to show the determined quantity of the analyte and the processed signals from the characteristic sensor. In addition, the characteristic monitor can include a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. Also, the sensor data signals can be received by the sensor receiver continuously, near continuously, and/or intermittently.

Description

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**CHARACTERISTIC MONITOR SYSTEM FOR USE WITH ANALYTE SENSOR****5    FIELD OF THE INVENTION**

10            This invention relates to characteristic monitors for use with sensor  
15            devices and, in particular embodiments, to characteristic monitors that include a  
             characteristic meter to facilitate testing and monitoring of a patient's condition  
             with coordination between continuous measurements and discrete measurements  
20            from a test strip, or the like.

**20    BACKGROUND OF THE INVENTION**

             Over the years, bodily characteristics have been determined by obtaining a  
             sample of bodily fluid. For example, diabetics often test for blood glucose levels  
25            with a blood glucose meter. Traditional blood glucose determinations have  
             utilized a painful finger stick using a lancet to withdraw a small blood sample that  
             is used by the blood glucose meter. This results in discomfort from the lancet as  
             it contacts nerves in the subcutaneous tissue. To obtain a measure of control or  
30            information on a diabetic's condition, several finger sticks and tests are required  
20            each day (8 or more such tests a day are not uncommon). The pain of lancing and  
             the cumulative discomfort from multiple needle sticks is a strong reason why  
             patients fail to comply with a medical testing regimen used to determine a change  
35            in characteristic over a period of time. In addition, these blood glucose meters are  
             only designed to provide data at discrete points, and even with multiple tests a  
25            day, do not provide continuous data to show the variations in the characteristic  
             between testing times.

40            A variety of implantable electrochemical sensors for use with monitors  
             have been developed for detecting and/or quantifying specific agents or  
             compositions in a patient's blood. For instance, glucose sensors have been  
45            developed for use in obtaining an indication of blood glucose levels in a diabetic  
30            patient. Such readings are useful in monitoring and/or adjusting a treatment  
             regimen which typically includes the regular administration of insulin to the

5 patient. Thus, blood glucose readings from the monitor improve medical  
therapies with semi-automated medication infusion pumps of the external type, as  
generally described in U.S. Patent Nos. 4,562,751; 4,678,408; and 4,685,903; or  
10 automated implantable medication infusion pumps, as generally described in U.S.  
5 Patent No. 4,573,994, which are herein incorporated by reference. Typical thin  
film sensors are described in commonly assigned U.S. Patent Nos. 5,390,671;  
5,391,250; 5,482,473; and 5,586,553 which are incorporated by reference herein.  
15 See also U.S. Patent No. 5,299,571. However, the monitors and electrochemical  
sensors often require calibration using readings obtained from blood glucose  
10 meters to augment and adjust for drift over time. Thus, although the monitors  
and electrochemical sensors provide more accurate trend information, a separate  
20 blood glucose meter is still often required.

#### SUMMARY OF THE DISCLOSURE

25 15 It is an object of an embodiment of the present invention to provide an  
improved characteristic monitor that is combined with a characteristic meter,  
which obviates for practical purposes, the above mentioned limitations.

30 According to an embodiment of the invention, a characteristic monitor for  
use in a system with at least one characteristic sensor that produces a signal  
20 indicative of a characteristic of a user includes a housing, a test strip receptacle, a  
sensor receiver and a processor. The test strip receptacle is for receiving and  
testing a test strip exposed to an analyte to determine the quantity of the analyte.  
35 The sensor receiver is used to receive sensor data signals produced from the at  
least one characteristic sensor. The processor is coupled to the sensor receiver  
25 and the test strip receptacle to process the determined quantity of the analyte and  
the sensor data signals from the at least one characteristic sensor. Preferably, the  
40 processor monitors the sensor data signals from the sensor receiver to determine  
when the test receptacle is to be used to perform calibration of the sensor data  
signals. Further embodiments include a transmitter coupled to the processor for  
45 transmitting the processed sensor data signals to another data receiving device.  
30 Preferably, the transmitter transmits the processed sensor data signals by radio  
frequencies. Still further embodiments include a display to show the determined

5 quantity of the analyte from the test strip receptacle and the processed sensor data  
signals from the at least one characteristic sensor. Additional embodiments  
include a memory to store the determined quantity of the analyte from the test  
strip receptacle and the processed sensor data signals from the at least one  
10 characteristic sensor. Also, the sensor data signals can be received by the sensor  
5 receiver continuously, near continuously, and/or intermittently.

In other embodiments, the processor includes the ability to program other  
medical devices, and the transmitter transmits the program to the other medical  
15 devices. Also, the transmitter transmits through a relay device between the  
transmitter and a remotely located processing device. In addition, the relay  
20 device increases a maximum distance by amplifying the processed sensor data  
signals from the transmitter to be received by the remotely located processing  
device, and the relay device enables the remotely located processing device to be  
located in a different room than the transmitter. Moreover, the relay device can  
25 include a telecommunications device, and when the transmitter generates an  
alarm the telecommunications device transmits the alarm to a remotely located  
receiving station.

In particular embodiments, the characteristic sensor is remotely located  
30 from the characteristic monitor, and the sensor receiver receives the sensor data  
signals as wireless signals from the remotely located characteristic sensor. In  
20 addition, the characteristic monitor can include a data receiver that is coupled to  
the processor to receive program instructions from other processing devices.

Further embodiments of the present invention are directed to a  
characteristic monitor for use in a system with at least one characteristic sensor  
35 that produces a signal indicative of a characteristic of a user including a housing,  
a second characteristic determining device, a sensor receiver and processor. The  
40 second characteristic determining device within the housing for receiving and  
testing an analyte to determine the quantity of the analyte independently of the  
characteristic sensor. The sensor receiver receives sensor data signals produced  
45 from the at least one characteristic sensor. The processor is coupled to the sensor  
30 receiver and the second characteristic determining device to process the  
determined quantity of the analyte from the second characteristic determining

5 device and the sensor data signals from the at least one characteristic sensor. The  
processor can monitor the sensor data signals from the sensor receiver to  
determine when the second characteristic device is to be used to perform  
10 calibration of the sensor data signals. In some embodiments, the at least one  
5 characteristic sensor is remotely located from the characteristic monitor, and the  
sensor receiver receives the sensor data signals as wireless signals from the  
remotely located at least one characteristic sensor. In additional embodiments,  
15 the characteristic monitor includes a transmitter that is coupled to the processor  
for transmitting the processed sensor data signals to another data receiving  
10 device. The characteristic monitor can include a display to show the determined  
quantity of the analyte from the second characteristic determining device and the  
processed sensor data signals from the at least one characteristic sensor. Other  
20 embodiments of the characteristic monitor can include a memory to store the  
determined quantity of the analyte from the second characteristic determining  
15 device and the processed sensor data signals from the at least one characteristic  
sensor. The characteristic monitor can receive the sensor data signals from the  
sensor receiver continuously, near continuously and/or intermittently.

In particular embodiments, the second characteristic determining device is  
30 a second characteristic monitor that utilizes a second characteristic sensor. For  
20 instance, the second characteristic monitor and the second characteristic sensor  
can use a different sensing technology from that used by the characteristic  
monitor and the at least one characteristic sensor. The second characteristic  
35 determining device can determine the quantity of the analyte continuously, near  
continuously and/or intermittently. In further embodiments, the second  
25 characteristic determining device utilizes a discrete sample to determine the  
quantity of the analyte, and the second characteristic determining device utilizes a  
40 test strip to analyze the sample to determine the quantity of the analyte.

Other features and advantages of the invention will become apparent from  
45 the following detailed description, taken in conjunction with the accompanying  
30 drawings which illustrate, by way of example, various features of embodiments  
of the invention.

**BRIEF DESCRIPTION OF THE DRAWINGS**

A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

Fig. 3 is a perspective view of a characteristic monitor with a characteristic meter in accordance with a second embodiment of the present invention.

Fig. 4 is a perspective view of a characteristic monitor with a characteristic meter for use with a telemetered glucose sensor and an infusion pump in accordance with a third embodiment of the present invention.

Fig. 5 is a simplified block diagram of a telemetered characteristic monitor transmitter and characteristic monitor in accordance with another embodiment of the present invention.

Fig. 6 is a simplified block diagram of a telemetered characteristic monitor transmitter and characteristic monitor system in accordance with still another embodiment of the present invention.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

As shown in the drawings for purposes of illustration, the invention is embodied in a characteristic monitor that obtains data from a sensor set that determines body characteristics on a continuous, near continuous or intermittent basis. In preferred embodiments of the present invention, the characteristic monitor includes a characteristic meter for obtaining discrete measurements that can be utilized by the characteristic monitor for calibration and/or data analysis and verification. Particular embodiments of the sensor set and monitor are for determining glucose levels in the blood and/or bodily fluids of the user.

However, it will be recognized that further embodiments of the invention may be used to determine the levels of other agents, characteristics or compositions, such as hormones, cholesterol, medication concentrations, viral loads (e.g., HIV), or the like. The characteristic monitor and sensor are primarily adapted for use with subcutaneous human tissue. However, still further embodiments may be placed with other types of tissue, such as muscle, lymph, organ tissue, veins, arteries or



5 the like, and used in animal tissue. The characteristic meter is primarily adapted  
for use with test strips that use a blood sample. However, still further  
embodiments of the characteristic meter may use other testing structures, such as  
10 liquid samples placed in a receptacle, or the like, or test strips that use samples  
5 from other fluids, such as interstitial fluid, spinal fluid, saliva, urine, tears, sweat,  
or the like. In still other embodiments, the characteristic meter may be replaced  
with another characteristic monitor that utilizes a different sensor technology than  
15 the first characteristic monitor, with the principal aim being to provide an  
automatic continuous, near continuous or intermittent comparison reading to  
10 calibrate and ascertain the accuracy of the data from the sensor connected to the  
first characteristic monitor.

20 Fig 1 illustrates a perspective view of a characteristic monitor system 10,  
in accordance with a preferred embodiment of the present invention. The  
characteristic monitor system 10 includes a subcutaneous sensor set 150 (i.e., a  
25 sensor portion is implanted in, for example, dermal subdermal, subcutaneous  
tissues, or the like), a telemetered characteristic monitor transmitter 100  
connected to the sensor set 150 through a sensor cable/connector 180, and a  
characteristic monitor 200 that includes a characteristic meter 300. The  
30 subcutaneous sensor set 150 utilizes an electrode-type sensors, as described in  
20 more detail in U.S. Patent. No. 5,391,250, entitled "Method Of Fabricating Thin  
Film Sensors", U.S. Pat. No. 5,482,473, entitled "Flex Circuit Connector", U.S.  
Patent No. 5,390,671, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent  
35 No. 5,568,806, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No.  
5,586,553, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No.  
25 5,779,655, entitled "Transducer Introducer Assembly" and co-pending U.S.  
Patent Application Serial No. 08/871,831, entitled "Disposable Sensor Insertion  
Assembly," all of which are herein incorporated by reference. However, in  
40 alternative embodiments, the sensor may use other types of sensors, such as  
chemical based, optical based, or the like. In further alternative embodiments, the  
45 sensors may be of a type that is used on the external surface of the skin or placed  
30 just below the skin layer of the user. Preferred embodiments of a surface  
mounted sensor would utilize interstitial fluid harvested from underneath the

5 skin.

10 The telemetered characteristic monitor transmitter 100 generally includes the capability to transmit data. However, in alternative embodiments, the telemetered characteristic monitor transmitter 100 may include a receiver, or the like, to facilitate two-way communication between the sensor set 150 and the characteristic monitor 200. The characteristic monitor 200 utilizes the transmitted data to determine the characteristic reading. Although a telemetered approach that utilizes RF is preferred, other wireless techniques, such as optical, IR, ultrasonic, or the like may be used. In addition, wired connections may be utilized instead of a telemetered transmission of data from the sensor 150 to the characteristic monitor 200 (see Fig. 3).

15 The characteristic meter 300 utilizes test strips 350, or the like, with a sample obtained from the body of the patient to determine a characteristic (or analyte level) in a user at a discrete point in time. The discrete measurement from the characteristic meter 300 is stored in a memory of the characteristic monitor 200 and may be used to calibrate the characteristic monitor 200 against the test results from the characteristic meter 300, either in real time or using a post calibration in either the characteristic monitor 200 or during later analysis and review once the test results have been downloaded to a separate computer, communication station, or the like. Possible characteristic meters 300 that may be used are produced by Roche Diagnostics, Bayer corporation, Abbott Medisense, Johnson & Johnson, Mercury Diagnostics, Chronimed, or the like.

20 Fig. 2 illustrates a simplified flow block diagram of the characteristic monitor 200 shown in Fig. 1. As shown in Fig. 2, the characteristic monitor 200 includes the characteristic meter 300 and also interfaces with a sensor set 150. The characteristic monitor 200 includes a key pad 202, a ROM 204, a RAM 206, a display 208, a data Input and Output (I/O) port 210, a sensor monitor 212, a sensor interface 214, a microprocessor 216, and a battery and/or power supply 218. The characteristic meter 300, included in the characteristic monitor 200, includes a characteristic test meter 302 and a test interface 304.

25 The microprocessor 216 of the characteristic monitor 200 is activated in several different ways. The keypad 202 is coupled directly to the microprocessor

5 216 and is useable to activate the microprocessor 216 so that the microprocessor  
216 is prepared to store relevant information concerning the sensor data, meter  
readings, event data, or the like. For instance, the microprocessor 216 will store,  
10 the time, the date and the analyte level from a test strip 350 or may be used to  
5 record an independent event by the user. In addition, the keypad 202 may be  
used to activate and control the microprocessor 216 to perform analysis,  
calibration, control the display 208, download stored data and results, upload  
15 program instructions, or the like. The microprocessor 216 may also be activated  
by receiving a specified signal from the sensor interface 214 indicating  
10 connection or receipt of data from a sensor 150 and/or by insertion of a test strip  
350 into the test interface 304 of the included characteristic meter 300. Once  
20 activated, the microprocessor 216 stores data, analyzes signal values, tests results  
for accuracy, calibrates, downloads data, presents data for review and analysis,  
provides instructions, warnings and alarms, or the like.

15 The microprocessor 216 is coupled to a ROM 204 and a RAM 206. In  
25 preferred embodiments, the ROM 204 is an EPROM and the RAM 206 is a static  
RAM; however, other comparable memory storage components such as dynamic  
RAM, non-static RAM, rewritable ROMs, flash memory, or the like, may be  
30 used. Generally, the ROM 204 stores the programs used by the microprocessor  
20 216 to determine various parameters, such as the amount of an analyte  
corresponding to a received signal value in the sensor monitor 212 signal value,  
calibration techniques for adjusting the sensor signals from the sensor 150,  
35 characteristic meter 300 operation and correspondence of test results with the  
sensor signal values, the date and the time, and how to report information to the  
25 user. The RAM 206 is used by the microprocessor 216 to store information about  
the sensor signal values and test strip 350 test results for later recall by the user or  
40 the doctor. For example, a user or doctor can transcribe the stored information at  
a later time to determine compliance with the medical regimen or a comparison of  
analyte value levels to medication administration. This is accomplished by  
45 30 downloading the information to the display 208 and then transcribing all of the  
stored records at one time as they appear on the display 208. In addition, the  
RAM 206 may also store updated program instructions and/or patient specific

5 information.

10 In preferred embodiments, the microprocessor 216 is coupled to a data input and output (I/O) port 210, and the user can download the stored information to an external computer (not shown), or the like, through the data I/O port 210 for  
15 evaluation, analysis, calibration, or the like. Preferably, the data I/O port 210 is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor. In preferred  
20 embodiments, the I/O port 210 uses infrared (IR) technology, such as that shown and described in U.S. Patent No. 5,376,070 entitled "Data Transfer System for an  
25 Infusion Pump", or the like, which is herein incorporated by reference. However, in alternative embodiments, the I/O port 210 may use other data transfer technologies such as cables, fiber optics, RF, or the like. In still other  
30 embodiments, the data I/O port 210 may include multiple ports to support multiple communication protocols or methods, or may include a universal port capable of transmitting data in several different modes. In preferred  
35 embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) a computer, communication station, or the like. In alternative embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) an infusion pump, or the like. In  
40 preferred embodiments, the characteristic monitor 200 is the approximate size of a conventional glucose meter or smaller. However, in alternative embodiments, the characteristic monitor 200 may be formed in larger sizes, comparable to a TV controller or a pocket calculator, and may include a larger display 208 to facilitate  
45 more complicated or easier programming.

50 The keypad 202 provides the user with the capability to store additional information, set the date and the time, or set alarms to indicate when to take the next test with the characteristic meter 300. The keypad 202 is used in  
55 conjunction with the display 208 to access the various modes, alarms, features, or the like, by utilizing methods typically employed to set the parameters on a conventional glucose meter, an infusion pump, or the like. The keypad 202 may also be used to manipulate the stored data in the characteristic monitor 200 and display the data on the on-board display 208.

5 The characteristic monitor 200 also includes a self contained battery and  
power supply 218. Preferably, the characteristic monitor 200 uses batteries (not  
shown) to provide power to the characteristic monitor 200. For example, a  
10 plurality of silver oxide batteries, such as two or three, may be used. However, it  
5 is understood that different battery chemistries may be used, such as lithium,  
alkaline or the like, and different numbers of batteries can be used. In preferred  
embodiments, the batteries have a life in the range of 1 month to 1 year, and  
15 provide a low battery warning alarm. Alternative embodiments may provide  
longer or shorter battery lifetimes, or include a power port or solar cells to permit  
10 recharging of rechargeable batteries in the characteristic monitor 200.

20 The ROM 204 of the characteristic monitor 200 also stores additional  
programs to operate and control the characteristic meter 300. Moreover, the  
RAM 206 of the characteristic monitor 200 can stores results obtained from the  
characteristic meter 300. As shown in Fig. 2, a test strip 350 for holding an  
15 analyte sample is inserted into the test interface 302. This activates the  
25 characteristic test meter 304 and the microprocessor 216. The characteristic test  
meter 304 analyzes the characteristics and sends the analysis results to the  
microprocessor 216, which displays the results on the display 208 and stores the  
results in the RAM 206 for later review.

20 The programs for controlling the sensor monitor 212 of the characteristic  
monitor 200 are also stored in the ROM 204, and sensor data signal values  
received by the sensor interface 214 from the sensor set 150 are processed by the  
35 sensor monitor 212 and the microprocessor 216, and then the results are stored in  
the RAM 206. The sensor monitor 212 and the sensor interface 214 can be  
25 activated by a wired connection to a sensor set 150 that draws power from the  
characteristic monitor, by receipt of a signal from the telemetered characteristic  
monitor transmitter 100, or by the keypad 202. Preferred embodiments use a  
40 characteristic monitor 200 (in which the system includes a Potentiostat such as  
sensor monitor 212) to receive the sensor signals from a telemetered  
45 characteristic monitor transmitter 100, as shown in U.S. Patent Application Serial  
No. 60/103,812 entitled "Telemetered Characteristic Monitor System and Method  
of Using the Same", which is herein incorporated by reference. In alternative  
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embodiments, the sensor signals may be received on a more infrequent (or periodic) basis from a Holter-type monitor system, as shown in U.S. Patent Application Serial No. 09/246,661 entitled "An Analyte Sensor and Holter-type Monitor System and Method of Using the Same", which is herein incorporated by reference.

Preferred embodiments store the raw received sensor signals values from the sensor monitor 212 and the test results from the characteristic test meter 304 of the characteristic meter in the RAM 206. However, alternative embodiments may also store calibrated and adjusted results in the RAM 206 for downloading, later analysis and review. Further embodiments may only store adjusted results.

Once activated, the sensor interface 214 continuously, intermittently or near continuously receives signals from the sensor set 150 that are representative of an analyte level being monitored in a user. In preferred embodiments, the sensor monitor 212 is used in conjunction with the microprocessor 216 to store, smooth the data and determine a corresponding analyte level from the signals received from the sensor interface 214. The corresponding value may be shown on the display 208. The characteristic monitor 200 may also perform calibration of the sensor signal values using values provided by the characteristic meter 300. The calibration may be performed on a real-time basis and/or backwards recalibrated (e.g., retrospectively). In further embodiments, the microprocessor 216 monitors the sensor signals from the sensor monitor 212 to determine when the characteristic meter 300 should be used to perform tests to be used for calibration of the sensor data signals. For instance, the microprocessor 216 could indicate that the calibration test should be delayed if the sensor data signals from the sensor monitor 212 are changing too rapidly and suggest a calibration reading when the sensor data readings are relatively stable. Also, the characteristic monitor may prompt the user to perform calibration at periodic preset intervals. Alternatively, the characteristic monitor may prompt the user to perform the calibration based upon event-triggered intervals, that are either user input, such as meals, exercise, or the like, or that are trend input, such as large excursions in glucose levels, faulty or interrupted data readings, or the like.

As shown in Figs. 1-4, the characteristic monitor 200 includes a display

5 208 that is used to display the results of the measurement received from the  
sensor in the sensor set 150 via a cable and connector 180 attached to the  
telemetered characteristic monitor transmitter 100, or the like. In preferred  
10 embodiments, the display device 208 is an active matrix LCD. However,  
5 alternative embodiments may use other display devices, such as simplified LCD,  
LED, fluorescent element, plasma screen, or the like. The results and information  
displayed includes, but is not limited to, trending information of the characteristic  
15 (e.g., rate of change of glucose), graphs of historical data, average characteristic  
levels (e.g., glucose), or the like. Alternative embodiments include the ability to  
10 scroll through the data. The display 208 may also be used with the keypad 202  
on the characteristic monitor 200 to program or update data in the characteristic  
20 monitor 200. In addition, the calibrated data using results from the characteristic  
meter 300 can be displayed to provide a user with updated trend and glucose level  
data. This may also be used to update and show differences between the newly  
25 calibrated (or additional calibration) data and the data as it was prior to the new  
calibration (or additional calibration).

In other embodiments, if multiple characteristic sensors are used, the  
individual data for each characteristic sensor may be stored and displayed to show  
30 a comparison and an average between the two characteristic sensors.

20 It is noted that a typical user can have somewhat diminished visual and  
tactile abilities due to complications from diabetes or other conditions. Thus, the  
display 208 and keypad 202 are preferably configured and adapted to the needs of  
35 a user with diminished visual and tactile abilities. In alternative embodiments,  
the data, analyte level value, confirmation of information, or the like can be  
25 conveyed to the user by audio signals, such as beeps, speech or the like, or  
vibrations. Still further embodiments may use a touch screen instead of (or in  
40 some cases addition to) the keypad 202 to facilitate water proofing and to  
minimize changes in the characteristic monitor 200 hardware to accommodate  
improvements or upgrades. Further alternatives may include a microphone (not  
45 shown) and related circuitry to allow voice activated control of the infusion  
30 device.

Additional embodiments of the present invention may include a vibrator

5 alarm (or optional indicator such as an L.E.D.) in either, or both, the telemetered  
characteristic monitor transmitter 100 and the characteristic monitor 200 to  
provide a tactile (vibration) alarm to the user, such as sensor set 150 malfunction,  
10 improper connection, low battery, missed message, bad data, transmitter  
5 interference, or the like. The use of a vibration alarm provides additional  
reminders to an audio alarm, which could be important to someone suffering an  
acute reaction, or where it is desirable to have non-audio alarms to preserve and  
15 conceal the presence of the characteristic monitor system 10.

As shown in Fig. 4, further embodiments of the characteristic monitor 200  
10 may be used with a telemetered characteristic monitor transmitter 100 coupled to  
a sensor set 150 and an infusion pump 400 connected to an infusion set 450. In  
this embodiment, the characteristic monitor 200 is also used to program and  
20 obtain data from the infusion pump 400, or the like. This further reduces the  
amount of equipment, the user must have, since the characteristic monitor 200  
15 already includes a characteristic meter 300 that will be required for calibration of  
the data from the telemetered characteristic monitor transmitter 100. Thus, the  
characteristic monitor 200 can coordinate the sensor data and meter data with the  
data from the infusion pump 400, or update the delivery parameters of the  
30 infusion pump 400. The characteristic monitor 200 may also be used to update  
20 and program the telemetered characteristic monitor transmitter 100, if the  
transmitter 100 includes a receiver for remote programming, calibration or data  
receipt. Thus, the user may need only a single device - the characteristic monitor  
35 200 that will receive data from a sensor set 150, perform discrete tests of an  
analyte with the characteristic meter 300, program and control an infusion pump  
25 400, and operate to download data or upload programming instructions to a  
computer, communication station, or the like.

As discussed, the characteristic monitor 200 can also be used to store data  
obtained from the sensor set 150 and then provide it to either an infusion pump  
400, computer or the like for analysis. In further embodiments, the characteristic  
45 30 monitor 200 can include a modem, or the like, to transfer data to and from a  
healthcare professional. Further embodiments, can receive updated programming  
or instructions via a modem connection. In addition, a relay or repeater 4 may be  
50



5 used with a telemetered characteristic monitor transmitter 100 and a characteristic monitor 200 to increase the distance that the telemetered characteristic monitor transmitter 100 can be used with the characteristic monitor 200, as shown in Fig.

10 5 For example, the relay 4 could be used to provide information to parents of children using the telemetered characteristic monitor transmitter 100 and the sensor set 150 from a distance. The information could be used when children are in another room during sleep or doing activities in a location remote from the parents. In further embodiments, the relay 4 can include the capability to sound an alarm. In addition, the relay 4 may be capable of providing data from sensor 10 set 150 and telemetered characteristic monitor transmitter 100 to a remotely located individual via a modem connected to the relay 4 for display on a monitor, pager or the like. In alternative embodiments, the data from the characteristic monitor 200 and sensor set 150 may also be downloaded through a communication station 8 (or alternatively, through a characteristic monitor 200, 25 other data transfer device, or the like) to a remotely located computer 6 such as a PC, lap top, or the like, over communication lines, by modem or wireless connection, as shown in Fig. 6. Also, some embodiments may omit the communication station 8 and use a direct modem or wireless connection to the computer 6. In further alternatives, either the characteristic monitor 200 or the 30 telemetered characteristic monitor transmitter 100 may transmit an alarm to a remotely located device, such as a communication-station, modem or the like to summon help. In addition, further embodiments of the characteristic monitor 200 may include the capability for simultaneous monitoring of multiple sensors. Data transmission may be to other devices or include the capability to receive data or 35 instructions from other medical devices. Preferred embodiments, as shown in Figs. 1 and 4, use wireless RF frequencies; however, alternative embodiments may utilize IR, optical, ultrasonic, audible frequencies or the like. Further embodiments may also use a wired connection, as shown in Fig. 3.

45 30 Preferably, the characteristic monitor system 10 combines the characteristic monitor 200 and character meter 300 into a single device, but avoids an actual wired connection to the sensor set 150 by using a telemetered characteristic monitor transmitter 100. By separating the characteristic monitor

5 system 10 electronics into two separate devices; a telemetered characteristic  
monitor transmitter 100 (which attaches to the sensor set 150) and a characteristic  
10 monitor 200, several advantages are realized. For instance, the user can more  
easily conceal the presence of the characteristic monitor system 10, since a wire  
5 will not be visible (or cumbersome), with clothing. In also makes it is easier to  
protect the characteristic monitor 200, which can be removed from the user's  
body during showers, exercise, sleep or the like. In addition, the use of multiple  
15 components (e.g., transmitter 100 and characteristic monitor 200 with a  
characteristic meter) facilitates upgrades or replacements, since one module or the  
10 other can be modified or replaced without requiring complete replacement of the  
characteristic monitor system 10. Further, the use of multiple components can  
20 improve the economics of manufacturing, since some components may require  
replacement on a more frequent basis, sizing requirements may be different for  
each module, there may be different assembly environment requirements, and  
25 modifications can be made without affecting the other components.

While the description above refers to particular embodiments of the  
present invention, it will be understood that many modifications may be made  
without departing from the spirit thereof. The accompanying claims are intended  
30 to cover such modifications as would fall within the true scope and spirit of the  
present invention.

The presently disclosed embodiments are therefore to be considered in all  
35 respects as illustrative and not restrictive, the scope of the invention being  
indicated by the appended claims, rather than the foregoing description, and all  
changes which come within the meaning and range of equivalency of the claims  
25 are therefore intended to be embraced therein.

## Claims

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WHAT IS CLAIMED IS:

1. A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user, the monitor comprising:

a housing;

test strip receptacle for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte;

a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor; and

a processor coupled to the sensor receiver and the test strip receptacle to process the determined quantity of the analyte from the test strip receptacle and the sensor data signals from the at least one characteristic sensor.

2. The characteristic monitor device according to claim 1, wherein the at least one characteristic sensor is remotely located from the characteristic monitor, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

3. The characteristic monitor device according to claim 1, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

4. The characteristic monitor device according to claim 3, wherein the transmitter transmits the processed sensor signals by radio frequencies.

5. The characteristic monitor device according to claim 3, wherein the processor further includes the ability to program other medical devices, and wherein the transmitter transmits a program to the other medical devices.

6. The characteristic monitor device according to claim 3, wherein the transmitter transmits through a relay device between the transmitter and a remotely located processing device.

5 7. The characteristic monitor device according to claim 6, wherein the relay device increases a maximum distance by amplifying the processed sensor data signals from the transmitter to be received by the remotely located processing device.

10 8. The characteristic monitor device according to claim 7, wherein the relay device enables the remotely located processing device to be located in a different room than the transmitter.

15 9. The characteristic monitor device according to claim 6, wherein the relay device includes a telecommunications device, and wherein when the transmitter generates an alarm the telecommunications device transmits the alarm to a remotely located receiving station.

20 10. The characteristic monitor device according to claim 1, further including a data receiver, and wherein the data receiver receives program instructions from other processing devices.

25 11. The characteristic monitor device according to claim 1, further including a display to show the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.

30 12. The characteristic monitor device according to claim 1, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the test receptacle is to be used to perform calibration of the sensor data signals.

35 13. The characteristic monitor device according to claim 1, further including a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.

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14. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver continuously.

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15. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver near continuously.

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16. The characteristic monitor device according to claim 1, wherein the sensor data signals are received by the sensor receiver intermittently.

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10 17. A characteristic monitor for use in a system with at least one characteristic sensor that produces a signal indicative of a characteristic of a user, the monitor comprising:

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a housing;

a second characteristic determining device within the housing for receiving and testing an analyte to determine the quantity of the analyte independently of the at least one characteristic sensor;

a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor; and

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a processor coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining device and the sensor data signals from the at least one characteristic sensor.

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18. The characteristic monitor device according to claim 17, wherein the at least one characteristic sensor is remotely located from the characteristic monitor, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

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19. The characteristic monitor device according to claim 17, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

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5 20. The characteristic monitor device according to claim 17, further including  
a display to show the determined quantity of the analyte from the second  
characteristic determining device and the processed sensor data signals from the  
10 at least one characteristic sensor.

5 21. The characteristic monitor device according to claim 17, wherein the  
processor monitors the sensor data signals from the sensor receiver to determine  
15 when the second characteristic determining device is to be used to perform  
calibration of the sensor data signals.

10 22. The characteristic monitor device according to claim 17, further including  
a memory to store the determined quantity of the analyte from the second  
characteristic determining device and the processed sensor data signals from the  
20 at least one characteristic sensor.

15 23. The characteristic monitor device according to claim 17, wherein the  
sensor data signals are received by the sensor receiver continuously.

30 24. The characteristic monitor device according to claim 17, wherein the  
sensor data signals are received by the sensor receiver near continuously.

35 25. The characteristic monitor device according to claim 17, wherein the  
sensor data signals are received by the sensor receiver intermittently.

40 26. The characteristic monitor device according to claim 17, wherein the  
second characteristic determining device is a second characteristic monitor that  
utilizes a second characteristic sensor.

45 27. The characteristic monitor device according to claim 26, wherein the  
30 determined quantity of the analyte from the second characteristic determining  
device is determined continuously.

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28. The characteristic monitor device according to claim 26, wherein the determined quantity of the analyte from the second characteristic determining device is determined near continuously.

10

5 29. The characteristic monitor device according to claim 26, wherein the determined quantity of the analyte from the second characteristic determining device is determined intermittently.

15

30. The characteristic monitor device according to claim 26, wherein the  
10 second characteristic monitor and the second characteristic sensor use a different sensing technology from that used by the at least one characteristic monitor and the characteristic sensor.

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31. The characteristic monitor device according to claim 17, wherein the  
15 second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte.

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32. The characteristic monitor device according to claim 31, wherein the  
20 second characteristic determining device utilizes a test strip to analyze the sample to determine the quantity of the analyte.

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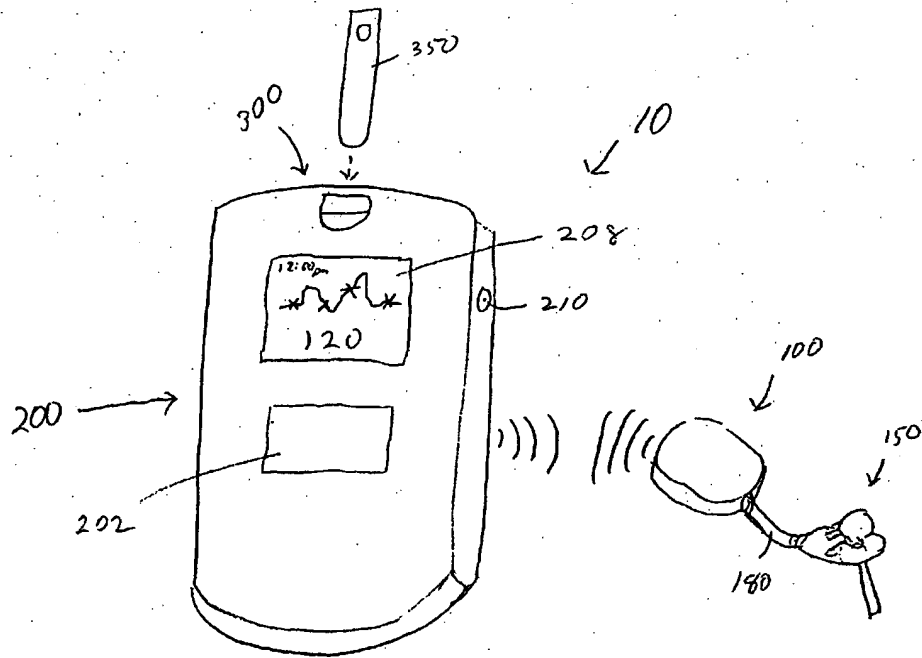


Fig. 1

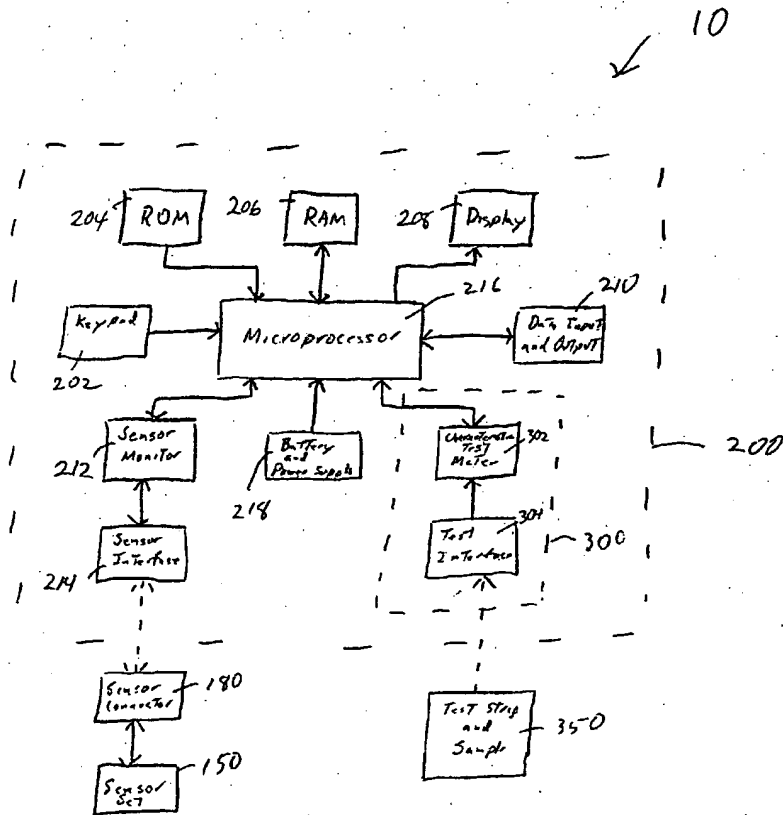


Fig. 2

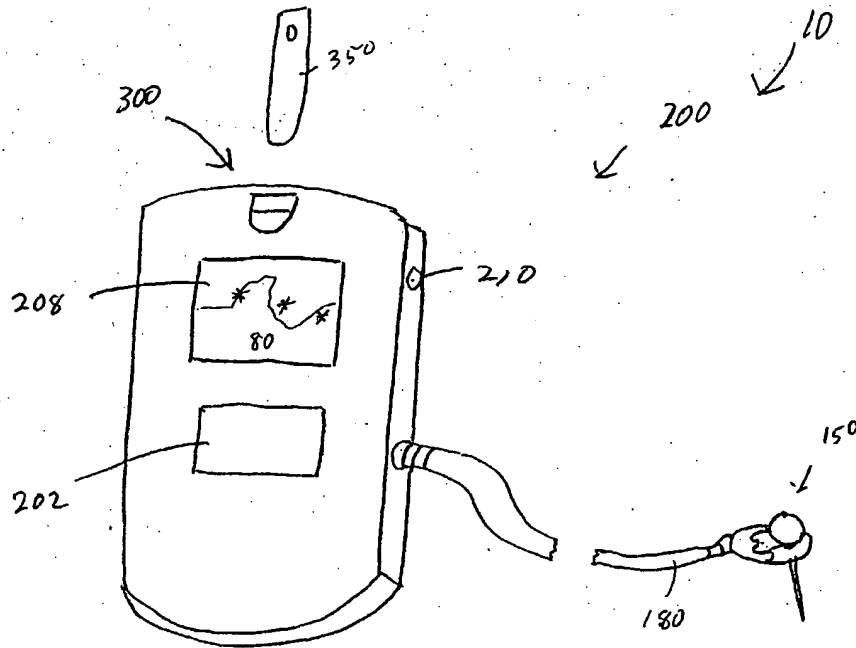
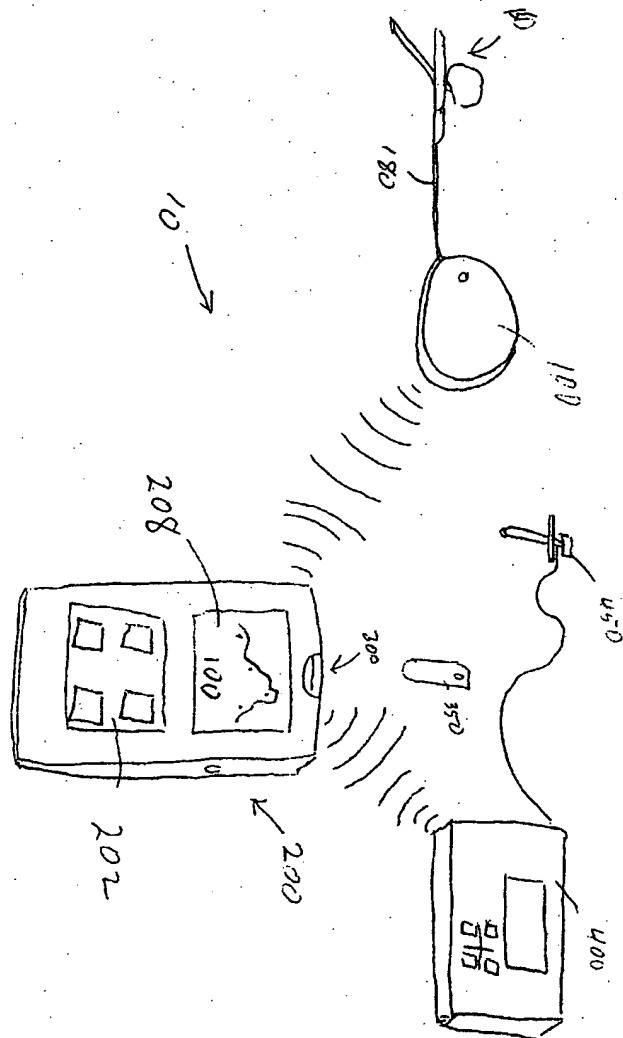


Fig. 3

Fig. 4



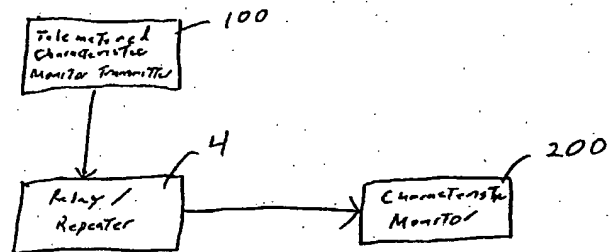


Fig. 5

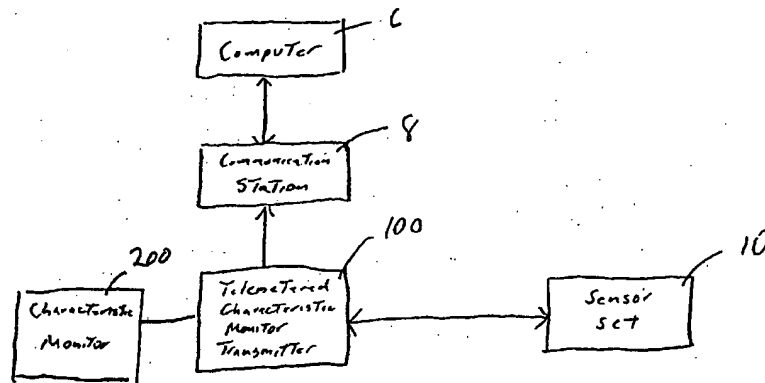


Fig. 6

# INTERNATIONAL SEARCH REPORT

Internat Application No  
PCT/US 00/16782

## A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 507 288 A (BOECKER DIRK ET AL) 16 April 1996 (1996-04-16)	1,2,11, 13-18, 20, 22-29, 31,32
Y	the whole document	
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Y	the whole document	
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Y	the whole document	
		6-8

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3 November 2000

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European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
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Chapple, I

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